

Reconsideration of the above-identified application and entry of the proposed amendment is requested in view of the following remarks.

REMARKS

Applicant wishes to thank the Examiner for the telephone interview granted on October 9, 2007. Although no agreement was reached Applicant believes the application is in condition for allowance.

Status of the Claims

Claims 1-16 and 30-32 are pending. Claims 1-16 and 30-32 have been rejected.

Claims 1 and 30 have been amended. The term “prevent” has been deleted as suggested by the Examiner at page 4 of the Office Action. As such, Applicant respectfully requests entry and consideration of the proposed amendment.

No new matter has been added.

Rejections under 35 U.S.C. § 112, paragraph 1

The Examiner has rejected claims 1-16 and 30-32 under 35 U.S.C. §112, first paragraph for failure to comply with the enablement requirement.

Applicant has deleted the term “prevent” from claims 1 and 30, as suggested by the Examiner. As such, Applicant believes this rejection has been rendered moot.

Rejections under 35 U.S.C. § 103

The Examiner has rejected claims 1-8, 10-16 and 30-32 under 35 U.S.C. §103(a) as being unpatentable over Zhang (U.S. Pat. No. 6,528,086). Applicant respectfully traverses this rejection.

Applicant respectfully asserts that Zhang does not teach or suggest the method presently claimed. Claim 1 of the present invention is directed to, “[a] method of treating healed wounds so as to reduce scarring and/or improve the appearance of scars comprises; applying onto a healed wound a composition comprising a fluid, film-forming carrier, and subsequently hardening the carrier into a tangible member juxtaposed to the healed wound thereby reducing scarring or improving the appearance thereof.” See claim 1 (emphasis added). As such, it is clear that the method presently claimed is directed to the reduction of scarring and requires applying the composition claimed onto a healed wound. This method is not taught or suggested by Zhang et al. Zhang et al. is broadly directed to a method and device for dermal drug delivery. According to Zhang et al. the composition of Zhang et al. is “applied to certain human body surfaces,” Zhang continues, “such as skin having an abrasion, laceration, or post-surgery wound.” See Zhang et al. at col. 1, lines 9-18. Zhang et al. does not disclose the application of the composition of Zhang et al. to healed wounds. Nevertheless, according to the Examiner, “skin conditions taught by Zhang (abrasions, lacerations, etc.) would be encompassed in and would included the ‘healed wounds’ instantly claimed by Applicant.” See Final Office Action at page 10, first full paragraph. Applicant respectfully disagrees with this contention. Moreover, Applicant respectfully asserts that abrasions, lacerations, and/or post-surgery wounds are not healed wounds, as presently claimed. Rather, as one of skill in the art would

appreciate, an abrasion, laceration, or post-surgery wound is a wound in need of healing, and not, as the Examiner contends, a healed wound.

The Examiner further points out, Zhang et al. goes on to list numerous drugs which can be delivered by the method and composition of Zhang et al. See the Final Office Action at page 6, second to last paragraph; see also Zhang et al. at col. 11, line 16 through col. 14, line 64. However, importantly Zhang et al. does not disclose any drugs for the treatment of, or reduction in appearance of scar tissue. In fact, Zhang et al. makes no mention of treating or reducing scar tissue whatsoever. As such, it is clear that Zhang et al. does not disclose or suggest the use of the composition to treat a healed wound and does not disclose or suggest reducing the appearance of scar tissue. Applicant respectfully asserts that Zhang et al. does not teach or suggest all the claim limitations of claim 1, and thus, claim 1 is not and cannot be rendered obvious by Zhang et al.

Again, Applicant strongly believes the invention as claimed is non-obvious. Nevertheless, the Examiner has maintained the § 103 rejection first issued in the Office Action dated October 11, 2006, and thus, appears to believe the invention as claimed to be obvious. As such, Applicant submits herewith the Declaration of Joel R. Studin under 37 C.F.R. § 1.131, showing the preparation of Scar Guard and its application to skin. According to the Declaration, Exhibit A shows the formulation of Scar Guard, which contains a corticosteroid in a film-forming carrier, and Exhibit C shows the application of Scar Guard on skin, both prior to September 28, 1999, the earliest filing date of Zhang et al. See the Declaration of Joel R. Studin at paragraphs 5-7. According to M.P.E.P., “where the differences between the claimed invention and the disclosure of the reference(s) are so small as to render the claims obvious over the reference(s), an affidavit or declaration under 37 C.F.R. 1.131 is required to show

no more than the reference shows.” See M.P.E.P. 715.02, Eighth Edition, Rev. Aug. 2006 at page 700-276 (emphasis added). Applicant respectfully points out that Zhang et al. does not teach the use of a film-forming carrier to treat a healed wound so as to prevent or reduce scarring, as presently claimed. See claim 1. At most, Zhang et al. teaches the application of a film-forming carrier to skin. Therefore, Applicant respectfully submits that the Rule 131 Declaration of Joel R. Studin, which shows the application of a film-forming carrier containing a corticosteroid to skin, is sufficient to antedate Zhang et al. Furthermore, Applicant respectfully directs the Examiner attention to dependent claim 5, which further claims, “wherein said composition includes an active ingredient capable of reducing scarring or improving the appearance of scars selected from a topical steroid, silicone-gel, vitamin and mixtures thereof.” See claim 5 (emphasis added). Applicant respectfully asserts that the Declaration of Joel R. Studin demonstrates possession of the invention as claimed in claim 5, prior to the effective date of the Zhang et al. reference. According to M.P.E.P., “[t]he 37 CFR 1.131 affidavit or declaration must establish possession of either the whole invention claimed or something falling within the claim (such as a species of a claimed genus). See M.P.E.P. 715.02 (emphasis added). Therefore, Zhang et al. is no longer an effective reference against the invention as claimed.

Applicant respectfully asserts that Zhang et al. does not and cannot render the presently claimed invention obvious. Likewise, claims 2-8, 10-16, which depend therefrom are not rendered obvious by Zhang et al.

Reconsideration and withdrawal of this rejection are respectfully requested.

Claim 30, like claim 1, is directed to a method to “prevent or reduce scarring and/or improving the appearance of scars” by “applying onto a healed wound” a

composition therefore. See claim 30 (emphasis added). As pointed out above, Zhang et al. does not disclose or suggest treating a healed wound or reducing the appearance of scar tissue. As such, Applicant respectfully asserts that claim 30, and claims 31-32 which depend therefrom, are not and cannot be rendered obvious by Zhang et al.

Furthermore, Applicant submits herewith the Rule 131 Declaration of Joel R. Studin, which renders Zhang et al. ineffective as a reference against the presently claimed invention, for the reasons stated above.

Reconsideration and withdrawal of this rejection are respectfully requested.

The Examiner has rejected claim 9 under 35 U.S.C. §103(a) as being unpatentable over Zhang (U.S. Pat. No. 6,528,086) in view of Tipton et al. (U.S. Pat. No. 5,632,727). Applicant respectfully traverses this rejection.

According to the Examiner, "Zhang teaches vitamins, such as vitamins A & D (see column 11, lines 32-33). [However,] Zhang does not teach Vitamin E." See Final Office Action at page 8, third paragraph. Furthermore, the Examiner states, "Tipton et al. ('727) teach a biodegradable film dressing and methods of using the film dressing to treat injured tissues and deliver biologically active agents within the film comprises vitamins, such as vitamin E (see reference column 10, lines 17-21)." See Final Office Action at page 8, fourth paragraph. According to the Examiner, "[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the vitamin E as taught by Tipton et al. within the delivery formulations of Zhang." See Final Office Action at page 8 fifth paragraph.


As Applicant has pointed out hereinabove, Zhang et al. does not disclose or suggest the application of the composition to a healed wound and does not disclose or suggest reducing the appearance of scar tissue. Furthermore, Applicant submits

herewith the Rule 131 Declaration of Joel R. Studin, which renders Zhang et al. ineffective as a reference against the presently claimed invention, for the reasons stated above. Tipton et al. does not make up for these deficiency. The biodegradable film of Tipton et al. "can be used to provide protection and promote healing of injured tissue and/or for delivery of biologically active agents or substances." See Tipton et al. at col. 2, lines 20-23 (emphasis added). According to Tipton et al., "the biological agent can act to enhance cell growth and tissue regeneration, cause nerve stimulation or bone growth, prevent infections, promote wound healing and/or provide pain relief." See Tipton et al. at col. 3, lines 25-30. Tipton et al. does not teach or suggest the application to a healed wound for reducing the appearance of scar tissue. As such, Applicant respectfully asserts that the combination of Zhang et al. and Tipton et al. does not and cannot render the presently claimed invention obvious.

Reconsideration and withdrawal of this rejection are respectfully requested.

Respectfully submitted,

Oct 9, 2007
Date


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